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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/820,656	04/08/2004	David K. Gong	50657-00004USPT	8010

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EXAMINER	
ALSTRUM ACEVEDO, JAMES HENRY	
ART UNIT	**PAPER NUMBER**
1616	

DATE MAILED: 07/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/820,656	GONG ET AL.	
	Examiner	Art Unit	
	James H. Alstrum-Acevedo	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 May 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-28 are pending. Receipt and consideration of Applicants' remarks/arguments submitted on May 22, 2006 is acknowledged.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claims 14-16 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating hemophilic bleeding, does not reasonably provide enablement for prevention of hemophilic bleeding in advance of a hemophilic assault **is withdrawn**, upon further consideration of the meaning of "prevention" in the context of hemophilic bleeding.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

The rejection of claims 17-26 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention **is withdrawn**, upon Applicants' clarification of the meaning of the term "monomeric" as applied to proteins during the telephonic interview on May 8, 2006 and consultation with Examiner Amber Steele, who has a background in microbiology and immunology.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of claims 17, 20, and 24-26 under 35 U.S.C. 102(b) as being anticipated by Lechuga-Ballesteros et al. (WO 01/32144; From IDS; "Lechuga") **is withdrawn**, upon further consideration.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejections of (1) claims 1-4, 6-10, 12-16, 18, 19, 21, 22, and 24 under 35 U.S.C. 103(a) as being unpatentable over Lechuga-Ballesteros et al. (WO 01/32144; From IDS; "Lechuga"); (2) claims 5-7, 11-13, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lechuga-Ballesteros et al. (WO 01/32144; From IDS; "Lechuga") as applied to claims 1-4, 6-10, 12-16, 18, 19, 21, 22, and 24 above, and further in view of Russell, K. E. et al. "Intratracheal Administration of Recombinant Human Factor IX (BENEFIX^{TM}) Achieves Therapeutic Levels in Hemophilia B Dogs" *Thromb. Haemost.* 2001, *85*, 445-449 (IDS); and (3) claims 27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lechuga-Ballesteros et al. (WO 01/32144; From IDS; "Lechuga") as applied to claims 1-4, 6-10, 12-16, 18, 19, 21, 22, and 24 above, and further in view of DeFrees et al. (US 2004/ 0137557) **are maintained** for the reasons of record set forth on pages 4-14 of the previous office action and expanded upon herein below. Claims 20 and 25-26 are added to rejection (1) above, and are now

rejected under 35 U.S.C. 103(a) as being unpatentable over Lechuga-Ballesteros et al. (WO 01/32144; From IDS; "Lechuga"), for the reasons of record.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The provisional rejections on the ground of nonstatutory obviousness-type double patenting of (1) claims 17-19 as being unpatentable over claims 1-11, 13-17, 22, and 39 of copending Application No. 10/313,343 (copending '343) in view of Platz et al., U.S. Patent No. 6,372,258 (USPN '258); and (2) claims 17-19 as being unpatentable over claims 41, 42, 54-58, 61-65, and 67 of copending Application No. 10/985,509 (copending '509) in view of Platz et al., U.S. Patent No. 6,372,258 (USPN '258) **are maintained** for the reasons of record set forth on pages 14-17 of the previous office action and as further explained herein below.

Response to Arguments

Applicant's arguments filed May 22, 2006 have been fully considered but they are not persuasive. Applicants' traverse the rejections of record because (1) an explicit teaching by the Lechuga reference concerning the quantity of monomeric factor IX present in compositions taught in and utilized in methods of treatment is lacking and (2) Applicant alleges that Lechuga requires the use of ethanol, which would result in compositions containing aggregated factor IX. Applicants' arguments are unpersuasive, because it is art recognized that biologically active factor IX is monomeric (i.e. it is comprised of a single polypeptide chain), as evidenced by the literature review of Kurachi, K. et al. ("Biology of Factor IX," *Blood Coagulation and Fibrinolysis*, **1993**, *4*, 953-974), wherein it is taught that "...mature plasma factor IX is a single polypeptide chain..." (pg. 954, right hand column, 2nd paragraph and Figure 2 on pg. 955).

Regarding the use of ethanol, Lechuga teaches that his compositions are made by dissolution of factor IX in water to obtain an aqueous formulation that is subsequently spray dried (pg. 17, lines 12-24; and Examples 2 and 7). The aqueous formulations ***may optionally contain*** additional water-miscible solvents, such as acetone, alcohols, and the like (pg. 17, lines 18-20). Therefore, Lechuga does not teach that ethanol or alcohols are required or even preferred in the preparation of his compositions, but merely that these may optionally be added. It would have been obvious to a person of ordinary skill in the art at the time of the instant invention to maximize the monomeric nature of factor IX compositions used in methods of treating hemophilia, because biologically active factor IX is art recognized as being monomeric.

Conclusion

Claims 1-28 are rejected. No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James H. Alstrum-Acevedo whose telephone number is (571) 272-5548. The examiner can normally be reached on M-F, 9:00-6:30, with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0664. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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